REMARKS

With this response, claims 71-86 and 89-110 are pending. Claims 89-92 have been amended without prejudice. Claims 71-85 were canceled as directed to non-elected subject matter. Claims 87, 88, 95, and 96 have also been canceled, without prejudice or disclaimer to the subject matter disclosed therein. Applicants reserve the right to prosecute the non-elected subject matter in divisional applications. Claims 98-110 have been newly added by way of the present amendment. Support for the foregoing amendment can be found throughout the specification, original sequence listing, tables, and the claims as originally filed, for example, in the specification at page 8, lines 19-28; page 31, lines 5-14; page 40, line 7 to page 42, line 13; page 91, lines 2-10; page 119, lines 4-16; and page 127, lines 13-22. No new matter is added.

I. Restriction Requirement

Applicants acknowledge the finality of the restriction requirement. Applicants reserve the right to file divisional applications containing the non-elected claims upon the finding of an allowable subject matter.

II. Claim Objections

Claims 86 and 89-97 have been objected to as being drawn to compounds in the context of a product-by-process format. The Examiner asserts that "product-by-process claim language is reserved for situations where the compound cannot be claimed in a definite manner...The instant application does not fall into this category, as the compounds are definite." Office Action at page 3. Applicants respectfully traverse the claim objections.

A product-by-process claim, which is a product claim that defines the claimed product in terms of the process by which it is made, is proper. *See In re Luck,* 476 F.2d 650, 177 USPQ 523 (CCPA 1973). A claim to a device, apparatus, manufacture, or composition of matter may contain a reference to the process in which it is made, so long as it is clear that the claim is directed to the product and not the process. *See* MPEP § 2173.05(p). Applicant respectfully

submit that they are claiming oil produced in a transgenic seed and not the process of making the oil in the transgenic seed.

At the outset, at least claim 86 is not in a product-by-process format, and as such, this objection does not apply to all pending claims as indicated by the Examiner. Applicants further assert that an oil is being claimed in the present invention. The claims recite, for example, "a first oil produced in a transgenic seed having an elevated level of a compound selected from the group consisting of sitosterol, at least one sitosterol ester, sitostanol, at least one sitostanol ester, and mixtures thereof, as well as a reduced level of a compound selected from the group consisting of campesterol, a campesterol ester, campestanol, a campestanol ester, and mixtures thereof, compared to a second oil produced by a corresponding non-transgenic seed." See Amended Claim 89. The claimed oil is a seed oil, not a blended or processed oil. For instance, Applicants could claim a non-blended oil, but instead choose here, as is their right, to describe the oil by how it is produced. Reconsideration and withdrawal of this objection are respectfully requested.

III. Rejections Under 35 U.S.C. §112, First Paragraph (Written Description)

Claims 86 and 89-97 have been rejected under 35 U.S.C. §112, first paragraph, for purportedly containing subject matter which was not described in the specification in such a way as to reasonably convey to one of skill in the art that the inventors, at the time the application was filed, had possession of the claimed invention. Office Action at page 3. Applicants respectfully disagree and traverse the rejection.

Applicants assert that the purpose of the written description requirement is to ensure that the inventors had possession of the claimed subject matter, *i.e.*, to ensure that the inventors actually invented what is claimed. *Gentry Gallery Inc. v. Berkline Corp.*, 134 F.3d 1473, 1479, 45 U.S.P.Q.2d 1498, 1503 (Fed. Cir. 1998); *Lockwood v. American Airlines*, 107 F.3d 1565, 1572, 41 U.S.P.Q.2d 1961, 1966 (Fed. Cir. 1997); *In re Alton*, 76 F.3d 1168, 1172, 37 U.S.P.Q.2d 1578, 1581 (Fed. Cir. 1996). A related and equally well-established principle of patent law is that claims "may be broader than the specific embodiment disclosed in a specification." *Ralston Purina Co. v. Far-mor-Co*, 772 F.2d 1570, 1575, 227 U.S.P.Q. 177, 179

(Fed. Cir. 1985), *quoting In re Rasmussen*, 650 F.2d 1212, 1215, 211 U.S.P.Q. 323, 326 (C.C.P.A. 1981).

The Examiner states that "Applicant does not describe other DNAs that encode all other steroid 5α-reductase enzymes from all organisms as broadly claimed." Office Action at page 4. (emphasis added). At the outset, Applicants are not claiming steroid 5α-reductases. Applicants claim oils that have been aptly described by the specification. By misconstruing the claims, the Examiner is not allowing Applicants to claim their invention as Applicants see fit. Applicants' claimed invention is drawn to oils, not recombinant DNA constructs. *See* Claims; Specification at page 33, line 17 to page 35, line 1. The Examiner's interpretation of the examined claims as being drawn to recombinant DNA constructs encoding steroid 5α-reductase is improper as a matter of law because it forces an improper examination of Applicants' invention. *See Appln. of Weber*, 580 F.2d 455, 458-459, 198 U.S.P.Q. 328, 332 (C.C.P.A. 1978). The *Weber* court, in particular, stated

> An applicant is given, by the statute, the right to claim his invention with the limitations he regards as necessary to circumscribe that invention, with the proviso that the application comply with the requirements of s 112. We have decided in the past that s 112, second paragraph, which says in part "(t)he specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention," allows the inventor to claim the invention as he contemplates it.

Appln. of Weber, 580 F.2d at 458. The Examiner apparently refuses to examine Applicants' claimed invention, and has instead incorrectly assumed that Applicants claim a recombinant DNA construct comprising a sequence encoding a steroid 5α-reductase enzyme. Office Action at page 4.

Moreover, Applicants respectfully disagree with the validity of Examiner's assertion that they have failed to adequately describe DNAs that encode all other steroid 5α-reductase enzymes from all organisms. The specification provides descriptions of the components of a recombinant construct, methods of constructing such constructs, and exemplary constructs used to transform cells, at, *e.g.*, page 29, line 7 to page 31, line 14, and page 86, line 17 to page 89, line 9. In addition, Applicants have provided a detailed chemical structure for nucleic acid sequences encoding steroid 5α-reductases (*e.g.*, SEQ ID NOs: 2, 4, 6, and 8) as well as detailed the deduced amino acid sequences (*e.g.*, SEQ ID NOs: 3, 5, 7 and 9) used to make the claimed oils in seeds.

Applicants have also described the function of, and uses for, these disclosed sequences, *e.g.*, to make the claimed seed oil. *See, e.g.*, sequence listing and specification at page 19, line 11 to page 21, line 25, page 42, line 19 to page 48 line 29, page 53, line 11 to page 58, line 11, and Examples 2, 7 and 9. Furthermore, the specification sets forth how to isolate nucleic acids encoding steroid 5α-reductases, and how to assay for elevated sterol and stanol levels in transformed plants. *See, e.g.*, page 53, line 11 to page 58, line 11 and Example 3 at pages 101-104. Applicants have also provided data to describe the composition of the claimed oils. *See, e.g.*, Table 5; Table 6; Specification at page 34, lines 23-27; page 106, lines 20-30; and page 109, lines 17 to page 110, line 2.

Furthermore, Applicants have described representative recombinant DNA constructs comprising steroid 5α-reductases in the Examples and elsewhere in the specification. In particular, Example 2 describes the construction of a vector containing a steroid 5α-reductase sequence such as SEQ ID NO: 2, 4, 6 or 8, the *Arabidopsis DET2* gene, or human steroid 5α-reductase. *See, e.g.*, specification at page 100-101. Example 7 also describes the transformation of a plant with a vector to create transgenic plants containing a nucleic acid molecule encoding a steroid 5α-reductase. *See* specification at page 110. *See also* specification at page 86 line 17 through page 98 line 20.

For the foregoing reasons, Applicants submit that one of ordinary skill in the art would recognize that at the time of filing Applicants were in possession of the claimed invention drawn to oils. Therefore Applicants respectfully request that the written description rejection under 35 U.S.C. §112, first paragraph, be withdrawn. Moreover, as the present Office Action does not demonstrate an examination of the claimed invention, Applicants respectfully request a revised Office Action from the Examiner. As such, Applicants also respectfully request that the next Office Action not be made final.

IV. Rejections Under 35 U.S.C. § 112, First Paragraph (Enablement)

Claims 86 and 89-97 were rejected under 35 U.S.C. §112, first paragraph, because the specification allegedly does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with

these claims. Office Action at page 5. Applicants respectfully disagree, and traverse the rejection. The Examiner has not met the evidentiary burden to impose an enablement rejection. A specification that discloses how to use a claimed invention "must be taken as in compliance with the enabling requirement of the first paragraph of § 112 unless there is reason to doubt the objective truth of the statements contained therein." *In re Brana*, 51 F.3d 1560, 1566, 34 U.S.P.Q.2d 1436, 1441 (Fed. Cir. 1995), *quoting In re Marzocchi*, 439 F.2d 220, 223, 169 U.S.P.Q. 367, 369 (C.C.P.A. 1971) (emphasis in original).

Applicants thank the Examiner for acknowledging that the specification is enabling for "claims limited to recombinant constructs comprising *Arabidopsis* and corn cDNAs encoding steroid 5α-reductase of SEQ ID NO: 2 and 4, as well as transformed host cells, transgenic plants and seeds." Office Action at page 5. However, the Examiner asserts that the specification allegedly does not enable any person of skill in the art to make and use the invention commensurate in scope with the claims. *Id.* Firstly, this assertion is unfounded because Applicants' invention, as originally claimed, is drawn to oils, and not recombinant constructs encoding steroid 5α-reductase. Applicants also respectfully assert that the specification enables any person of skill in the art to make and use the invention commensurate in scope with the claimed oils due to the reasons provided below.

The law makes clear that the specification need teach only one mode of making and using a claimed composition. *See Johns Hopkins Univ. v. CellPro, Inc.*, 152 F.3d 1342, 1361 (Fed. Cir. 1998). At least one mode of making the claimed oil is disclosed by the specification, satisfying the *Cellpro* requirement. As previously stated, the present specification indeed discloses how to make and use the present invention (*e.g.*, by providing protocols for identifying steroid 5α-reductase candidate nucleic acid sequences, and transforming plants with a nucleic acid encoding steroid 5α-reductase). *See, e.g.*, Examples 2, 7 and 9. Moreover, the present specification also discloses additional uses of the claimed oil (*e.g.*, to provide nutritionally enhanced oil compositions, including cholesterol-lowering compositions). *See, e.g.*, specification at pages 18-19.

The Examiner must provide specific evidence supporting the rejection or any explanation of why the specification allegedly fails to enable these uses. *See In re Wright*, 999 F.2d 1557,

1561-62, 27 U.S.P.Q.2d 1510, 1513 (Fed. Cir. 1993); *Ex parte Lemak*, 210 U.S.P.Q. 306, 307 (Bd. App. 1981) ("pure conjecture" does not substantiate rejection for lack of enablement). Therefore, as the specification teaches at least the methods of making and using the invention as set forth, for example, in the Examples, the enablement requirement has been satisfied. *See Johns Hopkins*, 152 F.3d at 1361 ("the enablement requirement is met if the description enables any mode of making and using the invention") (emphasis added), *quoting Engel Indus. v. Lockformer Co.*, 946 F.2d 1528, 1533, 20 U.S.P.Q.2d 1300, 1304 (Fed. Cir. 1991).

The Examiner alleges that "no guidance is provided in the specification for screening for the particular phenotype that would arise from over expression of steroid 5α-reductase" and "the isolation of orthologous cDNA's encoding steroid 5α-reductase would require making and testing of degenerate PCR primers and probes, as well as making and screening a multitude of cDNA libraries with those probes to isolate other cDNAs encoding steroid 5α-reductase." The Examiner therefore alleges that "undue experimentation would be required for one of skill in the art." Office Action at page 8. Applicants respectfully disagree with this assertion by the Examiner.

At the outset, Applicants are claiming oils, not steroid 5α-reductases. Furthermore, the amount of experimentation needed to attain the claimed oils might be extensive, but the experimentation is routine for one skilled in the art. If the techniques necessary to screen for a composition are obvious to those skilled in the art, the composition may be enabled. *See Ex Parte Kubin,* No. 2007-0819 (Bd. Pat. App. & Int. May 31, 2007). Further, it is well settled law that "the specification need not disclose what is well-known to those skilled in the art and preferably omits that which is well-known to those skilled and already available to the public." *See* MPEP § 2164; *In re Buchner*, 929 F.2d 660, 661, 18 U.S.P.Q.2d 1331, 1332 (Fed. Cir. 1991); *Hybritech, Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1384, 231 U.S.P.Q. 81, 94 (Fed. Cir. 1986), *cert. denied*, 480 U.S. 947 (1987); and *Lindemann Maschinenfabrik GMBH v. American Hoist & Derrick Co.*, 730 F.2d 1452, 1463, 221 U.S.P.Q. 481, 489 (Fed. Cir. 1984). Moreover, it is established patent jurisprudence that Applicants need not teach "conventional and well-known genetic engineering techniques." *E.g., Ajinomoto Co. v. Archer-Daniels-Midland Co.*, 228 F.3d 1338, 1345, 56 U.S.P.Q.2d 1332, 1337 (Fed. Cir. 2000). The specification only

needs to "supply the novel aspects of an invention in order to constitute adequate enablement." *See Genentech, Inc. v. Novo Nordisk,* 108 F.3d 1361, 1366, 42 U.S.P.Q.2d 1001, 1005 (Fed. Cir. 1997) (emphasis added). Whether or not an invention is enabled must be evaluated based on the state of prior art available as of the filing date of the application. *See* MPEP § 2164.

Applicants respectfully assert that the Examiner has not meet the burden to impose an enablement rejection and submit that, in fact, an analysis of the *Wands* factors support Applicants' position that the enablement requirement has been met for the claimed invention. *In re Wands*, 8 U.S.P.Q.2d 1400, 1404 (Fed. Cir. 1988). As presented in *Wands*, the criteria for ascertaining undue experimentation are 1) quantity of experimentation necessary, 2) the amount or direction of guidance presented, 3) the presence and absence of working examples, 4) the nature of the invention, 5) the state of prior art, 6) the relative skill of those in the art, 7) the predictability or unpredictability of the art, and 8) the breadth of the claims.

The first *Wands* criterion is the quantity of experimentation necessary. The "make-and-test" quantum of experimentation is reduced by knowledge, for example of conservative amino acid substitutions, degenerate nucleotide sequences, appropriate sequence identity ranges, assay conditions, screening methods for identifying the phenotype that would be produced from over expression steroid 5α-reductase, and methods for measuring the levels of elevated sterol and stanol levels in oils produced by transformed plants. *See, e.g.*, Specification at page 53, line 11 to page 58, line 11; pages 99-101; page 53, line 11 to page 58, line 11; and Example 3 at pages 101-104. Performing routine and well-known steps, such as an assay to measure levels of sterol and stanol levels in oils, for example, cannot create undue experimentation even if it is laborious. *In re Angstadt*, 537 F.2d 498, 504, 190 U.S.P.Q. 214, 218-219 (C.C.P.A. 1976).

The second and third criteria are the amount of direction or guidance given and the presence or absence of working examples. On these points, Applicants respectfully direct the Examiner's attention to the specification, where guidance is in fact provided in the form of working examples describing identification of steroid 5α-reductase amino acid and nucleic acid sequences, steroid 5α-reductase assays, and transformation of plants containing steroid 5α-reductase cDNA to obtain the claimed invention. *See, e.g.*, specification at pages 53-58 and the references cited at pages 51 and 53 (describing identification and isolation of steroid 5α-

reductase nucleic acid and amino acid sequences based on homology to known DET2 genes); pages 89-90 (describing plant transformation); and pages 99-101 (Examples 1-2) (describing elevation of sitostanol in seeds transformed with a vector comprising a steroid 5α-reductase-encoding DNA and methods of screening the same). Furthermore, the specification provides ample guidance for screening for the particular phenotype that would be produced from over expression of steroid 5α-reductase. *See* specification at page 31, lines 2-27. Applicants respectfully assert that they do not need to describe what is known in the art for the claimed invention to be enabled.

The fourth criterion focuses on the nature of the invention. The claims recite, for example, "a first oil produced in a transgenic seed having an elevated level of a compound selected from the group consisting of sitosterol, at least one sitosterol ester, sitostanol, at least one sitostanol ester, and mixtures thereof, as well as a reduced level of a compound selected from the group consisting of campesterol, a campesterol ester, campestanol, a campestanol ester, and mixtures thereof, compared to a second oil produced by a corresponding non-transgenic seed." See Amended Claim 89. Accordingly, practitioners in the art are guided not only by the specification itself but also by considerable resources available to one of skill in the art regarding conditions and approaches that can be utilized, for example, to isolate, confirm, and introduce into other hosts nucleic acid sequences to obtain oils within the scope of the claims. *See, e.g.,* references cited in the specification at pages 87 and 94. Such resources, combined with the specification and the art worker's own knowledge, provide ample guidance so that one of ordinary skill in the art is readily enabled to make and use the claimed invention.

The fifth and sixth criteria focus on the state of the art and the relative skill in the art. Methods helpful to practice the full scope of the invention such as sequence alignment, protein expression, and plant transformation are known. Moreover, the present specification itself adds to the relative skill in the art by providing detailed guidance regarding the application of such techniques to the art of the present invention. *See, e.g.*, Examples 1-11. The examples provide objective evidence that the relative skill in the art is sufficient to practice the claimed invention. Furthermore, the performance of routine and well-known steps, such as, for example, an assay to

confirm elevated sitostanol levels, cannot create undue experimentation even if it is laborious. *In re Angstadt*, 537 F.2d 498, 504, 190 U.S.P.Q. 214, 218-219 (C.C.P.A. 1976).

The seventh criterion considers the predictability of the art. The specification teaches the identification, expression, and confirmation of steroid 5α-reductase activity in recombinant constructs, transformed host cells, plants and seeds using the cDNA molecules disclosed in the present specification. Furthermore, the specification provides ample guidance for screening for the particular phenotype of oils that would be produced from over expression of steroid 5α-reductase in transformed plant cells. *See, e.g.,* specification at page 31, lines 2-27; pages 53-58; and the references cited at page 51.

The eighth criterion focuses on the breadth of the claims. Enablement is satisfied when the disclosure "adequately guide[s] the art worker to determine, without undue experimentation, which species among all those encompassed by the claimed genus possess the disclosed utility". *See In re Vaeck,* 947 F.2d 488, 496, 20 U.S.P.Q.2d 1438, 1445 (Fed. Cir. 1991). Here, enablement is satisfied because the art worker is specifically guided by the disclosure to look, for example, to analysis of tocopherols in plants to identify which species among all those encompassed by the claimed genus possess the disclosed utility.

Therefore, the Examiner's suggestion that the present application allegedly lacks enablement because undue trial and error experimentation would be required to screen through the "myriad of constructs comprising different DNAs encoding steroid 5α-reductase and plants transformed therewith" is incorrect. Office Action at page 7. To the extent that the Office Action suggests there is a requirement for *a priori* predictability without recourse to any experimentation, that position is without legal support. *Cf. Atlas Powder Co. v. E. I. du Pont de Nemours & Co.*, 750 F.2d 1569, 1576, 224 U.S.P.Q. 409, 413 (Fed. Cir. 1984) ("[t]hat some experimentation is necessary does not preclude enablement"). The proper test of enablement in such a situation is whether the disclosure "adequately guide[s] the art worker to determine, without undue experimentation, which species among all those encompassed by the claimed genus possess the disclosed utility." *See In re Vaeck*, 947 F.2d 488 at page 496.

The Examiner's "test" for enablement would require an art worker to be able, without even entering a laboratory, to name, for example, each and every steroid 5α-reductase sequence that results in overproduction of sterols and tocopherols in transformed plants. Firstly, Applicants are claiming oils, not steroid 5α-reductase sequences. Furthermore, the Examiner's above-mentioned test is not the *Vaeck* test. "It is well settled that patent applicants are not required to disclose every species encompassed by their claims, even in an unpredictable art." *In re Vaeck*, 947 F.2d at 496, 20 U.S.P.Q.2d at 1445. The *Vaeck* test recognizes proper enablement where the skilled art worker is able to determine oil levels produced in plants, especially as it is an oil that is claimed and not a steroid 5α-reductase sequence.

What is required for enablement of the claimed invention is that the art worker know how to determine, after reasonable experimentation, the composition of an oil produced in a seed. The Examiner has not contended, nor can one contend that this is unachievable with the claimed oils. Instead, an improper test has been manufactured and applied which requires (without legal authority) demonstration of *a priori* knowledge of whether a particular molecule would work as a steroid 5α-reductase to obtain the claimed invention.

For the foregoing reasons, Applicants respectfully request that the enablement rejection under 35 U.S.C. §112, first paragraph, be withdrawn. As the present enablement rejection does not demonstrate an examination of the claimed invention, Applicants respectfully request a revised Office Action from the Examiner. As such, Applicants also respectfully request that the next Office Action not be made final.

V. Rejection Under 35 U.S.C. § 101

Claims 86 and 89-97 were rejected under 35 U.S.C. § 101, as directed to non-statutory subject matter. According to the Examiner, "since the claim encompasses progeny that lack the transgene, the claim encompasses plants that are indistinguishable from plants that would occur in nature." Office Action at page 9. Applicants respectfully traverse the rejection.

Applicants assert that the Examiner's interpretation of the examined claims as encompassing progeny that lack the transgene is improper as a matter of law because it demonstrates an improper examination of Applicants' invention. See arguments above under 35

U.S.C. § 112 (written description). Applicants' claimed invention is drawn to oils. *See* Claims and Specification at page 33, line 17 to page 35, line 1. Applicants assert that the claimed oils have been aptly described and enabled as supported by the arguments above under 35 U.S.C. § 112 (written description and enablement). However, Applicants submit that this rejection is rendered moot by the claim amendments and that the amendments make clear that these claims are directed to an oil produced in a transgenic seed. Furthermore, regarding claim 86, the brassicastanol and stigmastanol described in the present specification have not been found to occur in nature, and thus the claimed oil containing these compounds are directed to statutory subject matter. See Claim 86 and Claims dependent thereof; and the specification at page 119, lines 4-16, page 127, lines 13-22. For the foregoing reasons, withdrawal of this rejection is respectfully requested.

VI. Rejection of Claims Under 35 U.S.C. § 102

Claims 86 and 89-97 stand rejected under 35 U.S.C. 102(b) as being anticipated by Fernholz *et al.* In rejecting the claims, the Examiner asserts that Fernholz *et al.* teaches an oil containing brassicasterol as one of its components which "reads on the instant oil, which only requires that one of the group consisting of brassicastanol, or its ester, stigmastanol, or its ester." Office Action at page 10. Applicants respectfully traverse the rejection.

At the outset, claim 89 does not recite the group consisting of brassicastanol, or its ester, and stigmastanol, or its ester. As such, this rejection does not apply to claim 89, and claims dependent thereof, namely claims 91, 92 and new claims 99-103. Furthermore, whatever else Fernholz *et al.* discloses, they do not disclose an oil comprising a compound selected from the group consisting of brassicastanol, at least one brassicastanol ester, stigmastanol, or at least one stigmastanol ester, and a mixture thereof as disclosed in the present specification. See Claim 86 and the specification at page 119, lines 4-16, and page 127, lines 13-22. As described in the specification, although phytostanols such as brassicastanol can be made commercially through hydrogenation of oils, in this process brassicasterol is hydrogenated to 22-dihydro-brassicastanol, in which both the C-5 and C-22 double bonds are reduced. Similarly, stigmasterol is hydrogenated to sitostanol, in which both the C-5 and C-22 double bonds are reduced. Fernholz

et al. do not describe a double bond at position C5 or C22 for either brassicastanol or stigmastanol as described in the specification. In fact, Fernholz *et al.* recite brassicastanol and stigmastanol without describing their structure. The brassicastanol and stigmastanol listed by Fernholz *et al.* are produced by hydrogenation outside of plants, unlike at least some of the oils of the claimed invention produced in seeds comprising a compound selected from the group consisting of brassicastanol, at least one brassicastanol ester, stigmastanol, or at least one stigmastanol ester, and a mixture thereof. For the foregoing reasons, Applicants respectfully assert that Fernholz *et al.* do not anticipate either brassicastanol or stigmastanol of the claimed invention and request withdrawal of this rejection.

CONCLUSION

In view of the above, each of the presently pending claims is believed to be in immediate condition for allowance. Accordingly, the Examiner is respectfully requested to withdraw the outstanding objection and rejections of the claims, and to pass this application to issue. The Examiner is encouraged to contact the undersigned at (202) 942-5186 should any additional information be necessary for allowance.

Respectfully submitted,

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